

Notice of Allowability

Application No.

10/716,170

Examiner

Janet L. Coppins

Applicant(s)

UNGASHE ET AL.

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the telephone conversation with Applicants' representative of 11/19/04.
2. ☒ The allowed claim(s) is/are 86-89.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

DETAILED ACTION

Claims 86-104 pending in the instant application.

Information Disclosure Statement

1. Applicants' Information Disclosure Statement (IDS), filed July 6, 2004, has been considered by the Examiner and entered of record in the file. Please refer to Applicants' copy of the 1449 form submitted herewith.

Response to Amendment

2. Receipt is acknowledged of Applicants' Preliminary Amendment, submitted October 4, 2004, which has been reviewed by the Examiner and entered of record in the file. Accordingly, claims 1-85 have been cancelled, and new claims 86-104 have been added.

Election/Restrictions

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:
- I. Claims 86-89 drawn to compounds and compositions, classified in class 546, subclass 347.
 - II. Claims 90-104, drawn to methods of using compounds according to formula (I), classified in class 514, subclass 358. A further election of a single disclosed disease to be treated will be required if this Group is elected.

The above Groups represent general areas wherein the inventions are independent and distinct, each from the other because of the following reasons:

4. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the

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product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product can be used in a materially different process of using that product, i.e. there are many recited used for the instant compounds, such as treating an inflammatory disease such as asthma or an unrelated disease such as leukemia or solid tumor. Therefore separate search conditions are involved, which would impose a burden if unrestricted.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and separate search conditions are involved, restriction for examination purposes as indicated is proper.

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be

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rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

7. During a telephone conversation with Ms. Shannon Mrksich, Reg. No. 36,675, on October 20, 2004, a provisional election was made without traverse to prosecute the invention of Group I, claims 86-89, drawn to compounds according to formula (I).
8. Claims 90-104 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.
9. Applicants have agreed to cancel the method claims in order to pursue them in divisional applications (please refer to the following Examiner's Amendment), therefore, in accordance with *In re Ochiai* and *In re Brouwer*, the Examiner withdraws the Restriction Requirement.

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10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Examiner's Amendment

11. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Ms. Shannon Mrksich on November 19, 2004.

12. The application has been amended as follows:

(a) Claim 87, please replace with the following:

87. The compound of claim 86 wherein the salt of the compound is selected from the group consisting of aluminum, ammonium, calcium, copper, ferric, ferrous, lithium, magnesium, manganic, manganous, potassium, sodium, or zinc.

(b) Claim 89, please replace with the following:

89. The composition of claim 88 wherein the salt of the compound is selected from the group consisting of aluminum, ammonium, calcium, copper, ferric, ferrous, lithium, magnesium, manganic, manganous, potassium, sodium, or zinc.

(c) Please cancel claims 90-104.

Allowable Subject Matter

13. Claims 86-89, in newly amended form, are now allowable over the prior art.

REASONS FOR ALLOWANCE

14. In view of Applicant's amendatory changes, cancellations and the Examiner's Amendment, claims 86-89 newly renumbered as claims 1-4, are allowable over the prior art. The following is an examiner's statement of reasons for allowance:

This invention relates to novel aryl sulfonamide compounds, and their compositions, that are active as CCR-9 antagonists. The claims in this case are 86-89, and the allowable compounds are limited to compounds according to formula (I). CCR-9 antagonists are known in the art as being useful for treating certain inflammatory disorders or diseases. However the aspect of preparing the instant claimed pyridinium-4-carbonyl-phenyl-benzenesulfonamide compounds is neither anticipated nor fairly suggested by the prior art. Applicants demonstrate the binding affinity of the instant compounds to the CCR-9 receptor through several *in vitro* receptor-ligand binding studies (pages 116-120), as well as migration assays, RAM assays, and the ability of the instant compounds to provide analgesic effects, shown in several animal (murine) models, found in pages 116-144 of the specification. After a thorough search, the closest of prior art WO 99/38845, was found to teach similar aryl sulfonamide compounds as PPARs (please refer to Example 3, for example). However the WO document fails to disclose the same compounds as instantly claimed, i.e. it does not teach the same pyridinium-4-carbonyl-phenyl-benzenesulfonamide compounds, or compositions thereof. Therefore, the prior art fails to teach, anticipate, or fairly suggest the instant claimed arylsulfonamides, or their use for treating CCR-9 mediated conditions.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

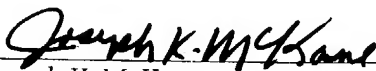
Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Coppins whose telephone number is 571.272.0680. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571.272.0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Coppins
December 6, 2004



Joseph K. McKane
SPE, Art Unit 1626